

REMARKS

The present application relates to inbred maize plant and seed PH8CW. Claims 1-34 are pending in the present application. Claims 7, 9 and 14 have been amended. No new matter has been added by way of amendment. Applicants respectfully request consideration of the claims in view of the following remarks.

Detailed Action

A. Specification

Applicants have amended the specification to include the U.S. Patent No. of the parent application on page 1. No new matter has been added.

B. New Matter

The Examiner has objected to the amendment filed 06/20/05 because it introduces new matter into the disclosure, specifically the last two sentences of the deposit paragraph which were amended to read "Unauthorized seed multiplication prohibited. U.S. Protected Variety." Applicants respectfully traverse and submit that the amendment is proper. The original deposit paragraph submitted on the filing date of the application states that "Applicant(s) do not waive any infringement of their rights granted under this patent or under the Plant Variety Protection Act (7 USC 2321 et seq.). Therefore as of the filing date of the application reference was made to the Plant Variety Protection Act (7 USC 2321 et seq). The last two sentences as amended by the Applicants are from the statutory language at 7 USC 2567, which provides that the variety may be marked "Unauthorized seed Multiplication Prohibited" and/or "U.S. Protected Variety". Applicants are providing the public notice of their statutory rights, and the added language is directly taken from the previously referenced statute. Applicants submit that this does not constitute new matter and respectfully requests reconsideration.

C. Claim Objections

The Examiner objects to claim 14 and suggests "wherein seed is allowed to form" be replaced with --harvesting the resultant seed--. Applicants have amended the claim as suggested by the Examiner, thus alleviating this objection.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 11-12, 23, 25-28 and 32-34 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regards as the invention. *See* Office Action, p. 3.

The Examiner states claim 11 is indefinite "for omitting essential steps".

Applicants traverse this rejection. Applicants have included " repeating steps (c) and (d) to produce backcross progeny plants that comprise the desired trait and comprise at least 95% of the alleles of inbred line PH8CW at the SSR loci listed in Table 4" in claim 11. Applicants further assert the use of molecular marker profiles by those of ordinary skill in the art in backcrossing is also clearly supported by the scientific literature. For example, see Ragot, M. *et al.* (1995) Marker-assisted backcrossing: a practical example, in *Techniques et Utilisations des Marqueurs Moleculaires (Les Colloques*, Vol. 72, pp. 45-56 (attached as Appendix 1), and Openshaw *et al.*, (1994) Marker-assisted Selection in Backcross Breeding, Analysis of Molecular Marker Data, pp. 41-43 (attached as Appendix 2). Specifically, Ragot *et al.* states in the first sentence of the summary "[t]hat molecular markers allow fast recovery of recurrent parent genotype in backcross programs is undisputed", and, in the first sentence of the introduction, "Backcrossing has been a common breeding practice for as long as elite germplasm has been available." Therefore, Applicants have claimed in the manner used by those of ordinary skill in the art to characterize backcross conversions, and 95% identity based on over 125 SSR markers is more than sufficient to characterize such conversions.

Claim 12 is rejected as indefinite "since the method of claim 11 lacks essential method steps".

Applicants traverse this rejection for the reasons asserted *supra*. Claim 12 is definite and does include the essential method steps of claim 11.

The Examiner further states that claims 23-28 are indefinite as the claims "do not incorporate all elements of the parent claim".

Applicants respectfully traverse. It would be understood by one of ordinary skill in the art that the deposited line can be manipulated and made male sterile by methods such as backcrossing, as described in the specification (for example, *see* pages 2 and 4, respectively). "It should be understood that the inbred can, through routine manipulation by detasseling, cytoplasmic genes, nuclear genes, or other factors, be produced in a male-sterile form"

(specification, p. 30, ll. 26-28). One of skill in the art also understands that transgenes can be incorporated into the inbred line in a similar manner (*see* pages 34-40). Male sterile conversions have been made to inbred lines since the 1950's, and transgenic conversions have been made to inbred lines since the early 1990's. Both are routinely made, and the language and meaning of these claims are well understood by plant breeders. The primary purpose of the requirement of definiteness of claim language is to "ensure that the scope of the claim is clear so the public is informed of the boundaries". MPEP § 2173. That objective has been satisfied by claims 23-28.

Claim 32 is rejected as indefinite in the recitation of "using" without any active method steps.

Applicants traverse this rejection. The specification states "[p]lant breeding techniques known in the art and *used* in a maize plant breeding program include, but are not limited to, recurrent selection, backcrossing, pedigree breeding, restriction fragment length polymorphism enhanced selection, genetic marker enhanced selection, making double haploids, and transformation. Often a combination of these techniques are used." (emphasis added, specification, p. 3). Therefore, Applicants assert that one of skill in the art would know the meaning of the term "using" in claim 32.

In light of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

Rejections Under 35 U.S.C. § 112, First Paragraph

Written description regarding Claims 1-12, 15-19, 21-26 and 29-34

Claims 1-12, 15-19, 21-26 and 29-34 stand rejected under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. The Examiner states the rejection is repeated for the reasons of record as set forth in the Office Action of March 17, 2005. The Examiner states "without a description of the sequences of the SSR markers, one cannot confirm the presence of the same SSR markers in any plant". The Office Action states that the "claims require the use of a multitude of non-exemplified molecular markers. The instant specification does not characterize or describe[d] even one maize molecular marker, with regard to sequence, length or source. Thus, the claims read on a method of using such products similarly inadequately described." *See* Office Action, p. 13.

Applicants respectfully traverse this rejection. Primers for the SSR markers listed in Table 4 are publicly available as stated in the present application. Applicants respectfully direct the Examiner's attention to p. 70, lines 12-15 of the specification where it states that "[p]rimers used for the SSRs reported herein are publicly available and may be found in the Maize GDB using the World Wide Web prefix followed by maizegdb.org (maintained by the USDA Agricultural Research Service), in Sharopova *et al.* (Plant Mol. Biol. 48(5-6):463-481), Lee *et al.* (Plant Mol. Biol. 48(5-6); 453-461), or reported herein". A print out from the MaizeGDB web site using bnlgl1014 as an example has been included with this response as Appendix 3. The print out shows the extensive amount of marker information available on the MaizeGDB, which includes primer sequences and map information. As explained in the specification, primer sequences for the public SSR markers listed in Table 4 can be easily obtained through the world wide web.

Further, Applicants assert that at least 95% of the alleles of inbred line PH8CW disclosed in the SSR profile of Table 4 is an identifying physical characteristic that describes the genus of minor variants of inbred line PH8CW, including, but not limited to, single locus conversions produced through transformation or introgression. The SSR profile of PH8CW is disclosed for numerous markers distributed throughout the genome as indicated by the Bin number of the marker, which denotes the marker location. A plant comprising 95% of the alleles of PH8CW as disclosed in Table 4 would be produced, for example, by repeated backcrossing to PH8CW. A backcross conversion of PH8CW as claimed in the instant application is described as comprising 95% of the alleles disclosed in Table 4.

It is undisputed that fingerprinting with molecular markers is widely used for characterizing germplasm. Specifically, SSR profiles are known and can be practiced by one of ordinary skill in the art in maize breeding. One of ordinary skill has been enabled by the deposit to make and use minor variants of inbred corn line PH8CW, and one of ordinary skill in the art uses SSR markers to characterize backcross conversions of an inbred. Applicants have claimed in the manner used by those of ordinary skill in the art to characterize backcross conversions.

Applicants also point out that molecular marker methods are known to one ordinarily skilled in the art and the SSR profile of PH8CW can be obtained from the deposit, but notwithstanding, Applicants have also provided the SSR profile of PH8CW in the application. *See* specification, Table 4, pp. 71-74 and U.S. Patent No. 6,784,349; Table 4, column 43, line 37

through column 45, line 25, respectively. Applicants reiterate that according to *Enzo*, the deposit of a material in a public depository is an adequate description of that material for purposes of the written description requirement. *Enzo Biochem, Inc.*, 296 F.3d at 1325, 63 U.S.P.Q.2d at 1613. In addition, *Regents of University of California*, 119 F.3d at 1568, 43 U.S.P.Q.2d at 1406, teaches that claims may satisfy the written description requirement where they disclose "structural features commonly possessed by members of the genus that distinguish them from others." The Board of Patent Appeals & Interferences has also confirmed the sufficiency of a deposit for seed and plants in the case of *Ex Parte C*, 1992 WL 515817 p. * 5, 27 U.S.P.Q.2d 1492, 1496 (B.P.A.I. 1992), where it stated that "[t]he claimed soybean is described in the specification to the extent that there is no question that appellant was in possession of the invention as of the time the instant application was filed. Because seed is to be deposited in a public depository, the specification is enabling and sets forth the best mode of carrying out the invention." Consistent with this principal, the Board of Patent Appeals & Interferences, in a case involving the written description requirement as applied to seed and plants, stated "[i]f in making the latter comment the examiner is requiring appellants to have reduced to practice each possible plant within the scope of the claims, such a position is legally incorrect. The specification need only teach one skilled in the art how to make and use the claimed invention. How the specification does so, whether by way of the written word or actual examples, is of no moment." *Ex parte Gerardu C.M. Bentvelsen et al.*, 2001 WL 1197757, p. *2 (B.P.A.I. 2001).

The Applicants further assert those of skill in the art utilize molecular markers, such as SSR's, to characterize plant genomes. As Applicants' clearly teach in the specification:

To accomplish this goal, the maize breeder must select and develop superior inbred parental lines for producing hybrids. This requires identification and selection of genetically unique individuals that occur in a segregating population. The segregating population is the result of a combination of crossover events plus the independent assortment of specific combinations of alleles at many gene loci that results in specific genotypes. *See* specification, p. 8, lines 14-19.

Further, Applicants teach:

In addition to phenotypic observations, the genotype of a plant can also be examined. A plant's genotype can be used to identify plants of the same variety or a related variety. For example, the genotype can be used to determine the pedigree of a plant. There are many laboratory-based techniques available for the analysis, comparison and characterization of plant genotype; among these are Isozyme Electrophoresis, Restriction Fragment Length Polymorphisms (RFLPs),

Randomly Amplified Polymorphic DNAs (RAPDs), Arbitrarily Primed Polymerase Chain Reaction (AP-PCR), DNA Amplification Fingerprinting (DAF), Sequence Characterized Amplified Regions (SCARs), Amplified Fragment Length Polymorphisms (AFLPs), Simple Sequence Repeats (SSRs) which are also referred to as Microsatellites, and Single Nucleotide Polymorphisms (SNPs). *See* specification, p. 20, lines 11-20.

Applicants also teach how the claimed backcross trait conversions are "routinely used and have a very high rate of success". *See* specification, p. 31, line 18. Those plants and plant parts that are developed substantially benefiting from the use of inbred maize line PH8CW "comprising a single gene conversion, transgene, or genetic sterility factor, may be identified by having a molecular marker profile with a high percent identity to PH8CW". *See* specification, p. 74, lines 12-15.

The use of molecular marker profiles by those of ordinary skill in the art in backcrossing is also clearly supported by the scientific literature. For example, see Ragot, M. *et al.* (1995) Marker-assisted backcrossing: a practical example, in *Techniques et Utilisations des Marqueurs Moleculaires (Les Colloques, Vol. 72, pp. 45-56* (attached as Appendix 1), and Openshaw *et al.*, (1994) Marker-assisted Selection in Backcross Breeding, Analysis of Molecular Marker Data, pp. 41-43 (attached as Appendix 2). Specifically, Ragot *et al.* notes that "spectacular" progress toward the recurrent parent genotype was obtained with 61 RFLP markers. Ragot *et al.* also concludes that "recovery of the recurrent parent genotype could proceed even faster than in the experiment described herein, should the appropriate protocol and resources (population size, number and position of markers) be allocated." In the case at issue, over 125 markers have been provided. SSR markers have been demonstrated to be at least as reliable, if not more so, than RFLP markers. *See* J.S.C. Smith *et al.*, An Evaluation of the Utility of SSR Loci as Molecular Markers in Maize (*Zea Mays* L.): Comparisons with Data from RFLPS and Pedigree, *Theor. App. Genet.* 95:163-173 (1997) (attached as Appendix 4). Accordingly, it is clear that at least 95% identity based on over 125 SSR markers is more than sufficient to characterize the claimed backcross conversions of PH8CW to one of ordinary skill in the art.

Thus, SSR profiles are known and can be practiced by one of ordinary skill in the art. One of ordinary skill has been enabled by the deposit to make and use backcross conversions of inbred corn line PH8CW, and one of ordinary skill in the art uses molecular markers to characterize backcross conversions of an inbred line. Applicants have claimed in the manner

used by those of ordinary skill in the art to characterize backcross conversions, and 95% identity based on over 125 SSR markers is more than sufficient to characterize such conversions.

The state of the art is such that it is routine to produce backcross conversions, a statement supporting by Ragot *et al.*, Openshaw *et al.*, as well as basic textbooks on plant breeding. For example, See Hallauer *et al.*, "Corn Breeding", Corn and Corn Improvement, No. 18, p. 472 (1988) and Poehlman *et al.*, Breeding Field Crop, 4th Ed., Iowa State University Press, Ames, IA, p. 334 (1995). Specifically, Ragot *et al.* states in the first sentence of the summary "[t]hat molecular markers allow fast recovery of recurrent parent genotype in backcross programs is undisputed", and, in the first sentence of the introduction, "[b]ackcrossing has been a common breeding practice for as long as elite germplasm has been available." The Applicants specification teaches that molecular markers of PH8CW can also be used to "reduce the number of crosses back to the recurrent parent needed in a backcrossing program". See specification, p. 6, lines 15-16. In fact, many of the transgenic corn lines currently being commercialized are the result of a backcross conversion of a novel inbred, such as PH8CW.

Similarly, the Examiner's assertion regarding the lack of availability of other inbred lines is also incorrect. There are a multitude of sources from which one may obtain other inbred lines. The National Plant Germplasm System is one such source, and its collection can be easily searched on the World Wide Web at ars-grin.gov/npgs/, where one can also find an on-line request form. A Compilation of North American Maize Breeding Germplasm, Gerdes, J.T., (1993) published by the Crop Science Society of America, has an extensive listing of inbred sources and specific lines available from public universities. Inbred lines are available from the ATCC as a result of deposits made in connection with patents as part of the *quid pro quo* of patent law. Thus, it is clear that contrary to the Examiner's assertion, many inbred lines that may be used as the second inbred line are readily available to the public. One of ordinary skill in the art would certainly know these and other public sources of inbred lines.

The Examiner also states "Applicants further assert that the genetic/morphological characteristics of all F1 hybrid seed/plants, produced from crossing inbred PH8CW with any other maize line, are not expected to vary from inbred PH8CW (response, paragraph bridging pages 8 and 9, and the last two full paragraphs of page 9.)" See Office Action, p. 7

The Examiner's quotation from the response filed on 06/16/05 is a misreading of Applicant's arguments. It is correct that "[i]t is well known to one ordinarily skilled in the art

that a hybrid made from an inbred will receive one set of chromosomes from that inbred parent" and that "when F1 hybrid seed is produced it will receive one complete set of chromosomes from the inbred parent, regardless of whether the inbred is used as the male or female parent of the F1 hybrid". It is also correct that the "genus of F1 hybrid seed and plants encompassed by Applicants' claims . . . all share the common structural attribute of having a complete or near complete set of the unique chromosomes of PH8CW" (emphasis added, paragraph bridging pages 8-9). Applicants have not stated that all F1 hybrids made with PH8CW would be phenotypically the same. It is true that genetics correlate with phenotype, and that the more highly related two individuals are genetically, the more similar their phenotype is likely to be. It is also true that if one desired to produce an F1 hybrid with the characteristics of the F1 hybrids disclosed in Table 3, one of skill in the art would prefer to utilize PH8CW rather than spending the time and resources to develop a novel inbred. However, the written description requirement does not mandate a description by phenotype. At its foundation, the written description requirement serves an evidentiary function of making certain that the Applicant's are in possession of a specific characteristic that identifies their claimed invention. The molecular marker data provided by Applicant's serves this purpose. The other inbred is not the point of patentability, nor is it what is being claimed. Rather, the claim is drawn precisely to what is described, an F1 hybrid with the identifiable and unique molecular profile of PH8CW.

Lastly, Applicants point out that the legal standards for the written description requirement do not mandate a description via phenotypic characteristics, i.e. plant height, leaf angle, leaf color, etc. Applicants respectfully refer the Examiner to the case of *Ex Parte Tanksley*, 37 USPQ2d. 1382. In that case, the Examiner desired that Tanksley claim according to sequence data to "better characterize the cDNA clones" and "facilitate a complete search of the prior art" and issued a § 112 first paragraph written description rejection. The Board held that "the section 112 rejection amounts to a requirement...that the appellants amend their claims in a specified manner...We find no language in the statute or case law which would support that requirement." The Board, in treating the section 112 first paragraph rejection as a § 112 second paragraph rejection, held that "[i]n our judgement, a patent Applicants is entitled to a reasonable degree of latitude in complying with the second paragraph of 35 U.S.C. § 112 and the examiner may not dictate the literal terms of the claims for the stated purpose of facilitating a search of the prior art. Stated another way, a patent Applicants must comply with 35 U.S.C. § 112, second

paragraph, but just how the Applicants does so, within reason, is within applicant's discretion." *Id.* at 1386.

Accordingly, Applicants submit that claims 1-12, 15-19, 21-26 and 29-34 are described. In light of the above amendments and remarks, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. § 112, first paragraph.

Double Patenting

The Examiner rejects claims 13-14 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 2 and 24-25 of copending U.S. Patent No. 6,784,349. The Examiner states that although the conflicting claims are not identical, they are not patentably distinct from each other because the claims in both application and the patent are directed to plants and parts thereof of PH8CW and methods of introducing a desired trait into said PH8CW plants by breeding methods and plants produced by said methods. *See* Office Action, p. 14.

Applicants are herein submitting a Terminal Disclaimer in compliance with 37 C.F.R. § 1.321(c), which disclaims any term of a patent issuing from this application which would extend beyond the term of copending U.S. Patent No. 6,784,349. Therefore, Applicants submit that the claims are in proper form for allowance and respectfully request reconsideration and withdrawal of the obviousness-type double patenting rejection.

Conclusion

In conclusion, Applicants submit in light of the above amendments and remarks, the claims as amended are in a condition for allowance, and reconsideration is respectfully requested. If it is felt that it would aid in prosecution, the Examiner is invited to contact the undersigned at the number indicated to discuss any outstanding issues.

Enclosed is our check for \$130.00 for the Terminal Disclaimer. No other fees or extensions of time are believed to be due in connection with this amendment; however, consider this a request for any extension inadvertently omitted, and charge any additional fees to Deposit Account No. 26-0084.

Reconsideration and allowance is respectfully requested.

Respectfully submitted,

A handwritten signature in cursive script, appearing to read "Lila A. T. Akrad".

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